Form "EAST Multicenter Stu Details #105 (submitted 04/	udy Proposal" (15/2020)
Study Title	Surgical Critical Care During COVID-19 Pandemic
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Are you a current member of EAST?	Yes
If you selected "No" above please identify a Sponsor that is an active EAST member:	
My Multicenter Study proposal is	Retrospective
Use this area to briefly (1-2 paragraphs only) outline the burden of the problem to be examined	The current pandemic of COVID-19 poses a real challenge to our healthcare system. While final counts are far from close, early reports from China demonstrate a high need for critical care resources for patients affected by the disease, with estimates around 5% of patients affected¬¬1. This was followed by reports from Italy, the second country to get heavily affected by the disease, regarding critical care reorganization in expectance of heavy ICU bed utilization2. As the number of cases have risen in the United States, becoming the country with the highest number of reported cases worldwide, critical care leaders provided reports of current resources available in US hospitals with suggested strategies for management of the pandemic, e.g. tiered critical care staffing3. Changes to the healthcare system extended to include surgical care. The American College of Surgeons released recommendations and guidance for surgeons including triaging and cancelling elective cases during the pandemic freeing up resources for use with COVID-19 patients like surgical intensive care beds, as well as possible close monitoring areas for critical patients like the post-operative care areas, and even the operating rooms. Surgical departments and chapters across the US have also started to provide data regarding the changes they adapted, with recommendations on restructuring in response to increased demands or the expected surge of ICU patients4,5. We aim to examine the changes of surgical critical care units in size, patient population, care models, and outcomes during the pandemic compared to a historical cohort and try to highlight areas for possible improvement in similar future scenarios.
Primary aim	Examine changes in surgical critical care units' patient population, diagnoses, care structures, and difficulties during COVID-19 pandemic.
Secondary aims	
Inclusion Criteria	All critical care units caring for surgical patients in the two periods: January-July, 2019 and January-July, 2020.
Exclusion Criteria	N/A

Therapeutic Interventions	There are no therapeutic interventions. This is a retrospective/observational analysis of critical practice.
Primary Outcome	ICU bed utilization by diagnosis
Secondary Outcomes	Mortality, ICU days, vent days, major complications. Unit team structures.

	Unit Variables:
	-Unit designation
	-Closed vs open unit
	-Total Number of ICU beds
	-Extended ICU location(s)
	-Extended ICU number of beds
	-Number of empty beds
	-Number of patients with surgical diagnosis
	-Number of patients with non-surgical diagnosis
	-Number of patients with COVID-19
	-Total number of intensivists in the unit
List specific variables to be collected & analyzed	-Number of medical intensivists
	-Number of anesthesiology intensivists
	-Number of surgical intensivists
	-Number of 12-hour shifts per intensivist
	-Number of critical care fellow
	-Average weekly hours per fellow
	-Number of non-ICU physicians
	-Number of 12-hour shifts per non-ICU physician
	-Total number of nurses available
	-Average daily number of working nurses
	-Average number of shifts per nurse
	-Total number of APPs
	-Average daily number of working APPs

-Average number of shifts per APP

-Number of residents

-Average weekly hours per resident

Patient Variables:

-Admission date and time

-Surgical vs Non-surgical vs COVID-19

-Demographics: Age, Race, Gender, Insurance status

-Comorbidities: Diabetes, Hypertension, Chronic Obstructive Pulmonary Disease, Coronary Artery Disease, Stroke, congestive heart failure, Atrial fibrillation.

-Primary diagnosis (Pre-operative if surgical)

-Primary procedure performed (if surgical)

-Care team (Surgical vs non-surgical)

-Team members involved in care

-Admission weight

-Weight within 48h of ICU discharge

-Volume of resuscitation in first 24 hours

-Total volume balance over ICU stay

-Units of PRBC/platelets/FFP transfused

-Volume of albumin given

-Days on vasopressors

-Vasopressors used

-Mechanical ventilation

-Ventilation mode(s)

-Ventilator days

-Tracheostomy day (from starting mechanical ventilation)

-Time of intubation

-Lowest P/F ratio

-Days with prone positioning

-Average hours of prone positioning

-Sedatives used

-Days on sedatives

-Frequency and duration of sedation break

-Antibiotics used

-Days on antibiotics

-Other scheduled medications

-Other PRN medications

-Indication for RRT

-Mode of RRT

-Day of initiation of RRT

-Days on RRT

-Anticoagulation agent and dose

-DVT/PE present on admission

-Time of diagnosis of DVT/PE

-Mobilization day and frequency

-Nutrition given

-Hospital acquired infections (VAP, CLABSI, CAUTI, C.Diff)

-ICU days

-Length of stay

Outline the data collection plan and statistical analysis plan succinctly After IRB and data use agreement approval, data will be collected from each participating hospitals' medical records via a retrospective chart review. A data collection tool that includes the variables of interest (as listed above) will be provided for all participating hospitals. Data will be aggregated and analyzed by our institution's statisticians. Descriptive analysis of practice patterns in management of different pathologies will be analyzed and grouped by unit model, designation, and intensivist training. Univariate analyses will be performed to investigate the relationship between those patterns and outcome variables. A multivariable logistic regression will be performed controlling for possible confounders and other variables of interest that were found to be significant in the univariate analyses (p-value < 0.1).

All data will be entered into RedCap by each individual site. The investigators will only be able to see their own data. All analysis will be done in an anonymized fashion.

Outline consent procedures here, if applicable	This is a retrospective / observational study and all data will be deidentified. Waiver of consent is requested.
Succinctly outline a risk/benefit analysis	This study is retrospective / observational, and data will be de-identified. This carries no more than minimal risk to patients. This study will provide insight into resource utilization in surgical critical care units in times of increased demand. Analysis of practice patterns and changes to adapt to the pandemic as well as difficulties can provide important information to develop guidelines and protocols ready in place for implementation in face of future pandemics.

Include a brief listing of key references	1. Wu Z, McGoogan JM. Characteristics of and Important Lessons from the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72?314 Cases From the Chinese Center for Disease Control and Prevention. JAMA. 2020;323(13):1239–1242. doi:10.1001/jama.2020.2648
	2. Grasselli G, Pesenti A, Cecconi M. Critical Care Utilization for the COVID-19 Outbreak in Lombardy, Italy: Early Experience and Forecast During an Emergency Response. JAMA. Published online March 13, 2020. doi:10.1001/jama.2020.4031
	3. Halpern NA, Tan KS, SCCM Ventilator Taskforce. U.S. Resource Availability for COVID- 19. Society of Critical Care Medicine. March 25, 2020
	4. Bank M, O'Neill P, Prince J, Simon R, Teperman S, Winchell R. Early Report from the Greater New York Chapter of the American College of Surgeons Committee on Trauma on the COVID-19 Crisis. April 13, 2020
	5. Zarzaur BL, Stahl CC, Greenberg JA, Savage SA, Minter RM. Blueprint for Restructuring a Department of Surgery in Concert with the Health Care System During a Pandemic: The University of Wisconsin Experience. JAMA Surg. Published online April 14, 2020. doi:10.1001/jamasurg.2020.1386